

Press Release

Independent Health Technology Assessment (HTA) confirms: The LiMAx Liver Function Test from Humedics GmbH has both clinical and health economic advantages

- Competence Center for Medical Devices (CCMD) publishes Mini HTA for LiMAx Test
- CCMD confirms and documents the clinical and economic advantages of the LiMAx Test for interventional use in liver surgery
- CCMD highlights the non-invasive breath test as particularly innovative

Berlin, 20/11/2019 - The Austrian Competence Center for Medical Devices (CCMD) has conducted a Mini Health Technology Assessment to identify and analyze the clinical and economic benefits, as well as the potential clinical risks of the LiMAx system from Humedics GmbH.

The institute confirms the clinical and health economic advantages of the LiMAx system for interventional use in liver surgery and highlights the non-invasive breath test as particularly innovative.

The unique Liver Maximum Capacity Test (LiMAx) quantifies the functional health of the liver, thereby enabling the planning of better and safer interventional liver procedures.

The HTA further concludes that the LiMAx system is a convenient and easy-to-implement way to reduce the cost of treatments associated with liver surgery. “For example, with 100 liver surgeries per year in a hospital, the use of the LiMAx system can save at least € 215,900 per year”.

"We are pleased and encouraged that this HTA confirms the validity and healthcare impact of our clinical study data, as well as many of our own

assessments of the potential benefits of the LiMAx test. This evaluation by independent experts shows that our unique diagnostic tool, which can measure the functional capacity of the liver in real time, not only helps patients and physicians alike, but also rewards the clinics and hospitals that choose to deploy the LiMAx test by providing them with considerable economic benefits”, says Karsten Damgaard-Iversen, Managing Director and Chief Executive Officer of Humedics GmbH, commenting on the publication of the CCMD Mini-HTA.

The HTA also investigated the non-interventional diagnostic use of the LiMAx test where published clinical study data show a wide range of use cases such as the diagnosis of non-alcoholic steatohepatitis, the detection of fibrosis/cirrhosis and the prediction of mortality. However, the HTA concludes that despite the promising results of these mainly retrospective studies, the clinical usefulness of the LiMAx system in non-interventional diagnostics cannot currently be confirmed with a sufficient level of evidence and that additional studies are needed.

“We are aware of the need for additional study data in other areas of clinical application of the LiMAx test, and we are therefore pleased that a large number of Investigator Initiated Trials (IITs) are currently ongoing, studying the utility and performance of our test in non-surgical areas such as transcutaneous liver interventions (e.g. SIRT, TACE & TIPPS), the diagnosis of NASH, LiMAx vs. Biopsy, monitoring of chronic liver diseases and chemotherapy toxicity”, Damgaard-Iversen further commented.

Liver diseases lead to approximately two million deaths per year worldwide. Currently available diagnostic options often prove to be of limited use for the exact measurement of liver function or for the prediction of various pathologies associated with the liver. A novel form of determining global liver function is the LiMAx test (Maximum Liver Function Capacity), which measures the metabolism of an intravenously administered solution (¹³C-methacetin) in the exhaled air of the patient. As no Health Technology Assessment for this test procedure has so far been conducted, the aim of this Mini Health Technology Assessment was to systematically evaluate and analyse the clinical evidence and the economic benefits of the LiMAx test.

Numerous diseases, such as malignant liver tumours, require the removal of parts of the liver, a so-called liver resection. In surgical management, the use of the LiMAx system leads to safer procedures and a reduction in postoperative intensive care unit days and hospital days. The economic cost-benefit analysis confirms the economic efficiency of the LiMAx system for use in surgical management, as costs savings between € 4.51 and € 23.54 for every Euro spent can be realized.

In addition, the LiMAx system features further clinical benefits such as for example reduced occurrence of postoperative liver failure and mortality and therefore, it can be recommended for application in everyday clinical routine.

To obtain a copy of the CCMD Mini HTA, please contact us at info@limaxtest.com.

For further information about Humedics and the LiMAx Test – please visit www.humedics.eu

About Humedics GmbH

Based in Berlin, Germany, **Humedics GmbH** is specialised in rapid and accurate liver function measurement using LiMAx[®], an innovative technology for analysing exhaled air. The LiMAx[®] test provides physicians with a method for quantitatively assessing an individual patient's liver function capacity within minutes. This enables physicians to select treatment strategies and follow disease progression based on up-to-date knowledge of the functional health of the liver. Current applications, which have already been published in prestigious medical journals, include liver function diagnosis before and after liver transplantation, surgical planning for liver surgery (such as assessing how much liver tissue can be removed without increasing the risk of acute liver failure), and assessment of liver diseases such as fibrosis and cirrhosis. At present, more than 25 studies regarding new diagnostic indications are being conducted. These include diagnosing and staging of chronic liver diseases such as non-alcoholic steatohepatitis (NASH), as well as selecting, monitoring and managing different oncology treatment options. These studies, initiated by researchers, have already provided evidence of further potential for the LiMAx[®] tests. The LiMAx[®] test is in routine clinical use at more than 30 leading university hospitals in Europe. So far, more than 20,000 LiMAx[®] tests have been performed. The LiMAx[®] test is commercially available in Germany, Austria and the UK.

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